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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,246	01/03/2002	Toshiaki Takezawa	2001-1784A	1296

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/980,246

**Applicant(s)**

TAKEZAWA ET AL.

**Examiner**

Vera Afremova

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group I, claims 1-13, in the reply filed on 7/14/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim.

Claims 1-13 are under examination in the instant office action.

***Claim Rejections - 35 USC § 112***

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 preamble is different from the preambles of depending claims as written. Thus, it is not particularly clear what product is claimed and how many distinct components are required in the claimed product. For example: it is unclear whether carrier of claim 1 is the same structural element as a support of claim 2. It is unclear whether a "tissue section" of claim 1 is a "culture of animal cells" of claim 1. It is unclear whether the "cell culture carrier" of claim 2 is the same as a "tissue section-containing carrier" of claim 1. It is unclear what are differences and structural relationship between claimed elements such as carrier, support, tissue section and culture of animal cells. It is unclear which of these 4 elements are required in the claimed product and which of them are simply intended uses and/or equivalent phrases.

Claim 7 is rendered indefinite by the phrase "to thereby introduce an exogenous physiologically-active agent into a specific site of the section" because it is neither clear what is encompassed by the claimed invention nor it is clear when read in the light of specification.

Regarding claim 8, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 9 is rendered indefinite by the phrase "previously" because it is uncertain what are final characteristics of the claimed product and what final characteristics of the claimed product have been modified by prior treatment such as freezing or embedding as encompassed by the claim. Is the claimed tissue frozen or embedded in paraffin and/or resin?

Claim 10 recites the limitation "plants" in the carrier of claim 1. There is insufficient antecedent basis for this limitation in the claim 1 because claim 1 is directed to an animal tissue section or a culture of animal cells.

Claims 12 and 13 are indefinite with respect to the phrases drawn to a tissue being "all of an unborn animal" or "all of a born animal".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. {Anat Embryol (1999) 199:319-327}.

Claims are directed to a tissue section-containing carrier wherein the carrier comprises an animal tissue section attached to a support. Some claims are further drawn to the use of the support that is glass and that is treated to promote tissue adhesion. Some claims are further drawn to the use of tissue that is fixed, treated with antibody, treated with reagents to modify its structure or that is embedded. Some claims are directed to the use of tissue derived from fetal or postnatal mammalian animal.

The references by Mori et al discloses a tissue section-containing carrier or a tube wherein the tube comprises an animal tissue section that is a preparation of mouse fetal or postnatal liver tissue section. The liver tissue section is mounted in a plasma clot on cover glass and, thus, it is attached to the support treated in order to promote tissue adhesion (page 320, col. 1, par. 2) and/or it is embedded in resin. The liver tissue section is fixed with methanol and treated with antibody (page 320, col. 2, par. 3). Thus, the cited reference teaches all claimed required elements as encompassed by the claimed invention. Therefore, the cited reference anticipates the claimed invention.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/12555.

Claims are directed to a cell culture carrier comprising an animal tissue section attached to a support. Some claims are further drawn to the use of treated plastic support. Some claims are further drawn to the use of tissue that is fixed, treated with antibody, treated with reagents to

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modify its structure or that has been frozen. Some claims are directed to the use of tissue derived from fetal or postnatal mammalian animal.

WO 99/12555 discloses a cell culture carrier or a well plate comprising an animal tissue section such as submucosal tissue attached to a plastic support or holder (example 3) and intended for animal cell culture. The plastic holder is flat in order to keep the tissue flat and thus, it is treated to promote tissue adhesion within the meaning of instant claims. The submucosal tissue is treated with enzyme galactosidase to remove surface epitopes and, thus, to modify tissue microstructure within the meaning of the instant claims. The cited patent teaches that the collection of submucosal tissue preparations includes freezing (page 12, line 29) and also includes treatment with antibodies (page 14, line 4) at least for the purpose of quality control of the submucosal tissue samples. The submucosal tissue preparations are obtained from mammalian animals (page 4, line 18). Although the cited document does not explicitly indicate whether born or unborn animals were used for tissue collections, it is reasonable to assume that both born and unborn animals have submucosal tissues and, thus, the submucosal tissue preparations used in the cell culture carrier of cited patent meets the meaning of instant claims 12 and/or 13. Therefore, the cited WO document anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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September 1, 2004

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

**VERA AFREMOVA**  
**PRIMARY EXAMINER**